Press Accounts

Researcher´s Fees Point to Other Potential Conflicts at NIH

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By David Willman

Government´s top expert on diabetes was paid by firm with stake in study he had role in. More `questionable´ payments surface.

WASHINGTON—In June 1996, a lawyer at the Department of Health and Human Services was reviewing financial statements filed each year by senior federal officials when one disclosure form caught his attention.

The government's top diabetes researcher reported taking money from the Warner-Lambert Co. while, in his official capacity, directing a nationwide test of a diabetes pill produced by the firm's drug unit, Parke-Davis. The lawyer became so concerned about a potential impropriety that he sent the researcher a memorandum under the heading "PROBLEMS NOTED."

"You should recuse yourself from all official matters involving Parke-Davis," wrote lawyer Paul J. Robertson. "If recusal would substantial[ly] interfere [with] the performance of official duties, you should divest all holdings."

Despite this warning, the researcher, Dr. Richard C. Eastman, through 1997 accepted $78,455 in compensation from Warner-Lambert and its affiliates, newly obtained records show. During the same period, Eastman oversaw the inclusion of the company's controversial pill, called Rezulin, in the National Institutes of Health's largest-ever study of diabetes.

Now, the unraveling of Eastman's arrangements has focused scrutiny on other potential conflicts of interest at NIH--along with the decisions of senior officials who permitted these relationships to occur. The newly obtained records and interviews reveal that:

An initial review over the last month at NIH has found that "approval of paid arrangements was questionable" for up to four other researchers. NIH officials have not provided the details of these new cases.
Since 1991, Eastman has collected at least $260,000 in consulting-related fees from a variety of outside sources, including six drug manufacturers. Eastman and NIH officials had earlier declined to specify the amount of money he had received.
Eastman accepted payments from at least four pharmaceutical companies that stood to gain from research he has directed at NIH. It previously was not known that Eastman had been paid by any firm, other than Warner-Lambert, that had a stake in the outcome of NIH studies he administered.
Two senior officials at NIH were put on notice of a potential conflict involving Eastman and voiced concern that he could stray beyond the bounds of federal law. But they approved Eastman's original and subsequent dealings with Warner-Lambert anyway.
HHS Inspector Investigates Ties

These new disclosures come at a time when the inspector general at Health and Human Services has begun investigating the ties between Eastman and Warner-Lambert. Eastman's dealings with the drug company, first reported by The Times on Dec. 7, has touched off a broad review of whether other such conflicts exist within NIH, the nation's presumed temple of objective scientific inquiry.

On Dec. 9, Eastman informed his superiors that he would immediately cease accepting income from outside employers, a spokeswoman for NIH Director Harold E. Varmus revealed this week.

"He has stopped all of his outside activities," Anne Thomas said. "The office of the director is very concerned about this issue."

Eastman, 52, receives $144,000 a year as the director of NIH's division of diabetes, endocrinology and metabolic diseases--making him among the highest paid officials in the U.S. government. He declined to comment for this article.

Warner-Lambert officials have said that their consulting arrangement with Eastman has been entirely proper.

The mixing of government and private roles by Eastman raises concerns because NIH recently has developed closer relationships with pharmaceutical and biotechnology companies. These firms stand to reap fortunes by developing breakthrough drug therapies jointly with NIH.

Several government and private-sector lawyers said they were puzzled why senior NIH officials permitted Eastman to take money from Warner-Lambert while overseeing a major study that had profound implications for the value of Rezulin and, potentially, the company itself.

"I am just amazed that the National Institutes of Health would allow a conflict of interest like that," said Michael S. Josephson, a Los Angeles lawyer whose nonprofit institute offers ethics counseling to federal officials and pharmaceutical companies. "It is not in the public interest for government physicians to have competing allegiances. And money creates a competing allegiance. This is a very troublesome conflict of interest."

Federal law makes it a crime for an official to participate "personally and substantially" in government matters that affect an outside employer. And ethics guidelines at NIH prohibit an official from engaging in private consulting if it would "interfere in any way" with the official's public responsibilities.

Warner-Lambert has reported that more than 1 million patients who suffer from adult-onset Type-2 diabetes have taken the pill. Since Rezulin was introduced in March 1997, sales have exceeded $1 billion.

But the success has not come without consequences: As of early December, the Food and Drug Administration linked Rezulin to at least 33 liver-failure deaths during its initial 21 months on the market in the U.S. and Japan.

FDA officials disclosed on Jan. 15 that they are now evaluating whether to narrow Rezulin's approved uses or to withdraw the drug. An FDA advisory committee has been assigned to reevaluate Rezulin at a March 26 meeting.

Officials at NIH withdrew Rezulin from its nationwide study--called the Diabetes Prevention Program--last June after the liver failure and death of a participant, a 55-year-old high school teacher from East St. Louis, Ill.

Eastman Records Not on Public File

The records that detail Eastman's arrangements with Warner-Lambert and other companies are not kept on public file. The Times recently obtained access to a portion of them under the Freedom of Information Act. However, the documents provided were censored to eliminate all information about the amount of time Eastman devoted to his outside clients.

The documents do show that Eastman vowed in March 1996 to "disqualify myself to judge or otherwise act [as a federal official] on any matter or matters pertaining to" Rezulin's status in the NIH study. Eastman also declared, beginning in fall 1995, that his official duties did not relate in any way to his work for Warner-Lambert.

Yet from 1994 through mid-1998 he was involved in a number of decisions, according to NIH records and interviews. Eastman participated in deliberations in 1994-95 assessing if Rezulin or other drugs should be selected for the study--and, from 1997 onward, whether Rezulin should be withdrawn because of liver-failure deaths among patients in general practice.

It was on June 10, 1996, that Eastman received the warning from the federal lawyer about discontinuing his work for Warner-Lambert. The next day, Eastman was quoted in a Warner-Lambert press release praising the drug in his capacity as a top government official.

Eastman has since denied making the statement; last month an NIH official asked Warner-Lambert to stop using his remarks.

Three of the other drug companies that have retained Eastman as a consultant--Eli Lilly, Becton Dickinson and Novo Nordisk--all have sought to benefit from the results of an earlier NIH study that Eastman helped oversee, the Diabetes Control and Complications Trial. The landmark 10-year study helped prove that vigorous control of blood sugar in juvenile-onset Type-1 diabetics cut the risk of eye disease.

Company officials said that Eastman was paid to confer with Becton Dickinson on "product development" and to attend "senior advisory meetings" at Novo Nordisk. A spokesman for Lilly did not provide comment. The three firms paid Eastman a total of $35,000 from 1994 to June 1998.

Concerns about Eastman's dealings with Warner-Lambert arose in November 1995, internal documents show. The qualms were voiced by Eastman's bosses, L. Earl Laurence, deputy director of NIH's diabetes institute, and the director, Dr. Phillip Gorden.

Laurence, in a Nov. 3, 1995, memo to an NIH lawyer, said that although he had recommended approval of Eastman's deal with Warner-Lambert two days earlier, Gorden had balked.

"After Dr. Gorden reviewed it, he expressed a concern that this activity may not be within law and regulation," Laurence wrote, adding: "I agreed with him that I shared his general concern. I would appreciate your review and advice before we proceed."

On Nov. 14, 1995, Laurence wrote in the file that he had talked with the lawyer "by phone."

The next day, Gorden approved Eastman's deal. Both Gorden and Laurence declined to comment.